NOV 19 2004

**VENTURE™ Anterior Cervical Plate System**
**Traditional 510(k) Summary – K042922**
**November 2004**

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

**Contact:** Richard Treharne
Sr. Vice President Regulatory Affairs

II. **Product Name:** VENTURE™ Anterior Cervical Plate System

**Classification Name:** Spinal intervertebral body fixation orthosis
**Classification No./Code:** 888.3060 - KWQ

III. **Description:** The VENTURE™ Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The implant components will be made from titanium alloy and may be supplied either sterile or non-sterile. The locking plate is manufactured from shape memory metal (Nitinol).

IV. **Indications:** The VENTURE™ Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

**WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.**

V. **Substantial Equivalence**: The subject VENTURE™ Anterior Cervical Plate System components were demonstrated to be identical to the predicate ORION® Anterior Cervical Plate screw and plate components cleared in K042235 and K042499. Comparison test data were provided in support of this notification. The sole purpose of this submission was to change the trade name of a subset of the ORION® Anterior Cervical Plate System to the VENTURE™ Anterior Cervical Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K042922
Trade/Device Name: VENTURE™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: October 19, 2004
Received: October 22, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

October 2004



510(k) Number (if known): _____

Device Name: VENTURE™ Anterior Cervical Plate System

Indications For Use:

The VENTURE™ Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

**Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.**

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhouse

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K042970000[illegible]